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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,817	09/22/1999	JAMES P. KOCH	01996/005001	3842

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EXAMINER
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BROWN, MICHAEL A

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

**Office Action Summary**

Application No.

09/400,817

Applicant(s)

James P. Koch

Examiner

Michael Brown

Group Art Unit

3764

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- ☒ Claim(s) 1-3, 5-6, 8-17, 19-36, 39-50 and 57-59 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 28-32 and 57 is/are allowed.
- ☒ Claim(s) 1-3, 5-6, 8-17, 20-25, 27, 33-36, 39-48 and 58-59 is/are rejected.
- ☒ Claim(s) 19, 26 and 49-50 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

**Application Papers**

- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119 (a)-(d)**

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some\* ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

**Attachment(s)**

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3, 5-6,, 8-17, 19-36, 39-50 and 57-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not clear as to what the exocervix is. Applicant has not definition of what the exocervix is.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 5-6, 10-11, 44-46 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipfert in view of Goepp '318.

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Lipfert discloses in figures 1-17 a cervical cap, substantially as claimed. However, Lipfert does not disclose the cap dome being custom-molded. Goepp teaches in figures 1-8 a cervical cap that is custom formed (custom-molded). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the cervical cap dome as disclosed by Lipfert could be custom-molded as taught by Goepp in order to provide a better fit between the cervical cap and the vagina. Thus, allowing the user to be able to prevent fluids from being exchanged because of the custom fit.

5. Claims 17, 20 and 23-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shields in view of Goepp '318.

Shields discloses in figures 1-8 a cervical cap, substantially as claimed. However, Shields does not disclose the cap dome being custom-molded. Goepp teaches in figures 1-8 a cervical cap that is custom formed (custom-molded), as set forth immediately above. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the cervical cap as disclosed by Shields could be custom-molded as taught by Goepp for the reason set forth immediately above.

6. Claims 8-9, 12-17, 21-25, 27, 41-43 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipfert in view of Shields, as set forth in the previous office action, Paper No. 13, along with Goepp.

Goepp teaches in figures 1-8 a custom form (custom-molded) cervical cap. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that

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therapeutic agent and the ring as taught by Shields could be incorporated into Lipfert in order to use the ring to absorb and destroy sperm via the spermicide. It is inherent that the membrane could be any desired thickness.

7. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipfert in view of Goepp, along with Koch '436.

Lipfert discloses a cervical cap, substantially as claimed. Goepp teaches custom-molding the cervical cap. Koch '436 teaches in figure 1 a cervical cap 10 having a rim 130 that has a plurality or raised protrusions (152, 154 and 156). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the protrusions on the rim as taught by Koch '436 could be incorporated into the cervical cap as disclosed by Lipfert and taught by Goepp in order to use the protrusions to grip the uterus when the cap is placed into position within the vagina.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 33-36, 39-40 and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goepp '318.

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***Allowable Subject Matter***

10. Claims 19, 26 and 49-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. Claims 28-32 and 57 are allowed.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. No additional prior art was cited during the first office action.
13. Any inquiry concerning this communication should be directed to Michael Brown at telephone number 308-2682.

M. Brown  
February 20, 2003



Michael A. Brown  
Primary Examiner